

REMARKS

I. INTRODUCTION

Applicants respectfully traverse the Examiner's assertion that the Amendment filed March 8, 2010 is non-responsive. As discussed in detail below, the Examiner's analysis provided in the Notice of Non-Responsive Amendment dated July 6, 2011, is technically incorrect and fails to comply with the provisions of M.P.E.P § 803. For these reasons, Applicants requests reconsideration of the Office Action response dated March 8, 2010. In the sections below, Applicant's attorney reviews the reasons relied upon by the Patent Office for finding the Amendment filed March 8, 2010 non-responsive, and then identifies why this analysis is in error.

II. THE PATENT OFFICE'S RATIONALE FOR FINDING A NON-RESPONSIVE AMENDMENT

The Patent Office's rationale for finding the Office Action response dated March 8, 2010 non-responsive is reproduced in part below:

The claims, as would be amended, are not readable on the elected invention for the following reasons:

Claims 32-34, as would be amended, are directed to a method of attracting T lymphocyte or mature host dendritic cells to a site of a spontaneous genetically identical tumor in a mammal (claim 32), an autologous tumor (claim 33), or a lung cancer tumor in a human (claim 34).

In contrast the originally presented claims were directed to a method of attracting T lymphocyte or mature host dendritic cells to a site of a spontaneous syngeneic tumor in a mammal.

Thus, the claims, as would be amended, are directed to patentably distinct subject matter, the examination of which would require new and different considerations and searches not before necessary; and as such, examination of the claims, as would be amended, would be unduly burdensome.

Here, since the originally presented and newly claimed inventions are patentably distinct, and because the examination of both one could not be made without serious burden, it is proper to restrict each from the other. See M.P.E.P. §803.

III. SPECIFIC REASONS WHY THE RATIONALE IS IN ERROR

As noted below, the finding of non-response is in error because, as shown by the multiple dictionary definitions cited herein, the claims presented in the Amendment filed March 8, 2010 clearly read on the elected invention. These dictionary definitions shown that those of skill in this art understand that the language in claims 32-34 merely uses art accepted terminology to describe the originally elected subject matter.

A. Technical Dictionaries Confirm That Amended Claim 32 Recites Terms Having the Same Essential Characteristics of the Subject Matter Disclosed in the Originally Presented Claims

M.P.E.P § 806.03 states that “[w]here the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, **restriction therebetween should never be required**. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition.”

In determining the definitions of terminology as used by those skilled in the art, courts have noted, for example that “the help that technical dictionaries may provide to a court ‘to better understand the underlying technology’ and the way in which one of skill in the art might use the claim terms.” *Vitronics*, 90 F.3d at 1584 n.6. “Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention.” *See Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002).

Attached to this response is an Appendix having excerpts from a number of different general dictionaries and medical/technical dictionaries which confirm that the term “syngeneic” is defined as “genetically identical.” For this and other reasons, those of skill in this art would not agree with the Examiner’s belief that these terms fail to define the same essential characteristics. Illustrating this, a number of excerpts from these dictionary definitions are reproduced below.

1. Oxford Dictionary (<http://www.oxforddictionaries.com>): **Syngeneic** – (of organisms or cells) **genetically similar or identical** and hence immunologically

compatible, especially so closely related that transplantation does not provoke an immune response

2. The American Heritage Medical Dictionary (© 2007, 2004 by Houghton Mifflin Company): **Syngeneic** (adj.) - **Genetically identical** or closely related, so as to allow tissue transplant; immunologically compatible
3. Merriam-Webster Medical Dictionary (<http://www.merriam-webster.com/medical/>)
Syngeneic – **genetically identical** especially with respect to antigens or immunological reactions
4. Dorland's Medical Dictionary for Health Consumers (© 2007 by Saunders, an imprint of Elsevier, Inc.): **Syngeneic** – denoting individuals or tissues that have **identical genotypes** and thus could participate in a syngraft
5. Mosby's Medical Dictionary, 8th edition (© 2009, Elsevier):
 1. denoting an individual or cell that has the **same genotype** as another individual or cell.
 2. denoting tissues that are antigenically similar. Also isogenic.

In view of, for example, the dictionary definitions that are reproduced above, one of skill in the art would agree that a claim that substitutes the term “syngeneic” with “genetically identical” merely uses slightly different terminology to describe the same essential subject matter. One of skill in the art would not agree with the Examiner’s belief that these terms describe patentably distinct subject matter. For these reasons, claim 32 as amended in the Amendment dated March 8, 2010 is clearly readable upon the originally elected invention.

B. Claims 33 and 34 Recite Terms Having the Same Essential Characteristics of the Subject Matter Disclosed in the Originally Presented Claims

Those of skill in the art would further agree that an “autologous tumor in a mammal” and a “lung cancer tumor in a human” are both a “spontaneous genetically identical tumor in a mammal.” In one illustration of this, the McGraw-Hill Concise Dictionary of Modern Medicine (© 2002 by The McGraw-Hill Companies, Inc.) defines “autologous” as “referring to a tissue that comes **from the same person**, in contrast to that donated by another person” (see Appendix below). Being

from the same person, an autologous tumor, by definition, will also be a genetically identical tumor. Similarly, a lung cancer tumor in a human also has the same genotype of the human. The newly presented claims 33 and 34 are further not distinct from claim 32 because the methods directed toward an “autologous tumor in a mammal” and a “lung cancer tumor in a human” would not be patentable over the method directed towards a “spontaneous genetically identical tumor” since both the autologous tumor and the lung cancer tumor are tumors with the same genotype as the host (i.e. genetically identical tumors). For these reasons, new claims 33 and 34 as presented in the Amendment dated March 8, 2010 are clearly readable upon the originally elected invention.

C. The Examiner’s Analysis Fails to Comply with the Provisions of M.P.E.P §§ 802.01, 803, 806.05, 806.06 and 808.01

Under M.P.E.P § 803, “the claims of an application may properly be required to be restricted to one of two or more claimed inventions **only if they are able to support separate patents and they are either independent (MPEP § 802.01, § 806.06, and § 808.01) or distinct (MPEP § 806.05 - § 806.05(j))**.” M.P.E.P 802.01 states that “[t]he term “independent” (i.e., unrelated) means that there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect.” Furthermore, “[r]elated inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is patentable (novel and nonobvious) over the other (though they may each be unpatentable over the prior art).”

As shown by the dictionary definitions that reproduced above, those of skill in the art would agree, for example, that a “spontaneous genetically identical tumor” and a “spontaneous syngeneic tumor,” define the same essential characteristics. For this reason, they are related (i.e., not independent). The format of the claims further confirms this because, for example, both original and amended claim 32, use the terms “spontaneous genetically identical tumor” and a “spontaneous syngeneic tumor” to describe the same method for the same effect (i.e. using secondary lymphoid tissue chemokine to attract T lymphocytes or mature host dendritic cells to the site of a tumor). Therefore, these inventions are not only related (i.e., not independent), but also not distinct, because, for example, a method directed towards a “spontaneous genetically identical tumor” would

obviously not be patentable over an identical method directed towards a “spontaneous syngeneic tumor.”

As noted above, the methods recited in amended claim 32 (and new claims 33 and 34) are neither independent nor distinct from the method recited in original claim 32. For this reason, the Examiner’s analysis fails to comply with the provisions of M.P.E.P § 803. The Notice of Non-Responsive Amendment should therefore be withdrawn.

D. The Examiner’s Analysis Further Fails to Comply with the Provisions of M.P.E.P § 808.02

As noted in M.P.E.P § 803, if the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct invention. For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant.”

As noted above, a “spontaneous genetically identical tumor” and a “spontaneous syngeneic tumor” are merely different words describing the same subject matter. Consequently, a separate classification, separate status in the art or different field of search would not be required for the newly presented claim 32. Furthermore, because both an “autologous tumor in a mammal” and a “lung cancer tumor in a human” are types of a “genetically identical tumor in a mammal,” a separate classification, separate status in the art or different field of search would also not be required for the newly presented claims 33 and 34. Therefore, examination of the newly presented claims would not be a serious burden on the examiner. Moreover, Applicant respectfully notes that no support was provided in the Notice of Non-Responsive Amendment to show any specific separate classifications, fields of search, etc. that could be applicable to the originally and newly presented claims. Consequently, the Examiner’s analysis fails to comply with the provisions of M.P.E.P § 808.02. For this additional reason, the Notice of Non-Responsive Amendment should be withdrawn.

IV. REQUEST FOR RECONSIDERATION

Because the Notice of Non-Responsive Amendment was erroneously predicated on the Patent Office's view that the newly presented claims were drawn to a non-elected invention, Applicant respectfully submits that the Notice of Non-Responsive Amendment is in error. A reconsideration of the Amendment dated March 8, 2010 is respectfully requested.

V. CONCLUSION

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge all fees to Deposit Account No. 50-0494 of Gates & Cooper LLP.

Respectfully submitted,

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APPENDIX

SYNGENEIC DEFINITIONS

1. Oxford Dictionary (<http://www.oxforddictionaries.com>): Syngeneic – (of organisms or cells) **genetically similar or identical** and hence immunologically compatible, especially so closely related that transplantation does not provoke an immune response.
2. The American Heritage Medical Dictionary (© 2007, 2004 by Houghton Mifflin Company): Syngenic (adj.) - **Genetically identical** or closely related, so as to allow tissue transplant; immunologically compatible.
3. Merriam-Webster Medical Dictionary (<http://www.merriam-webster.com/medical/>) Syngeneic – **genetically identical** especially with respect to antigens or immunological reactions.
4. Dorland's Medical Dictionary for Health Consumers (© 2007 by Saunders, an imprint of Elsevier, Inc.): Syngeneic – denoting individuals or tissues that have **identical genotypes** and thus could participate in a syngraft.
5. Mosby's Medical Dictionary, 8th edition (© 2009, Elsevier):
 1. denoting an individual or cell that has the **same genotype** as another individual or cell.
 2. denoting tissues that are antigenically similar. Also isogenic.

AUTOLOGOUS DEFINITIONS

1. McGraw-Hill Concise Dictionary of Modern Medicine (© 2002 by The McGraw-Hill Companies, Inc.): Autologous – *adjective* Referring to a tissue that comes from the **same person**, in contrast to that donated by another person. Cf Heterologous, Homologous.
2. Gale Encyclopedia of Medicine (© 2008 The Gale Group, Inc. All rights reserved.): Autologous – From the **same person**. An autologous breast reconstruction uses the woman's own tissues. An autologous blood transfusion is blood removed then transfused back to the same person at a later time.
3. Dorland's Medical Dictionary for Health Consumers (© 2007 by Saunders, an imprint of Elsevier, Inc.): Autologous – related to self; belonging to the same organism.